

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-2133V

Filed: April 24, 2025

SHERRI PULSIPHER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Master Horner

Jimmy A. Zgheib, Zgheib Sayad, P.C., White Plains, NY, for petitioner.

Rachelle Bishop, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

On November 4, 2021, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa, *et seq.* (2012),² alleging that she suffered a Table Injury of a shoulder injury related to vaccine administration (“SIRVA”) as a result of an influenza (“flu”) vaccination she received on October 24, 2020. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is *not* entitled to compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

¹ Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists SIRVA as a compensable injury if it occurs within ≤48 hours of administration of a flu vaccine. § 300aa-14(a), *amended by* 42 C.F.R. § 100.3. Table Injury cases are guided by a statutory “Qualifications and aids in interpretation” (“QAI”), which provides more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. § 300aa-14(a). To be considered a Table SIRVA petitioner must show that his/her injury fits within the following definition:

SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of

radiculopathy, brachial neuritis, mononeuropathies, and any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, a petitioner could still demonstrate entitlement to an award by instead showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). To successfully demonstrate causation-in-fact, petitioner bears a burden to show: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 300aa-13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; see also *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3(b)(1). Special masters must ensure each party has had a "full and fair opportunity" to develop the record. Vaccine Rule 3(b)(2). However, special masters are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or

death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” § 300aa-13(b)(1)(A). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec’y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines ex rel. Sevier v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

II. Procedural History

Based on the allegations in the petition, this case was initially assigned to the Chief Special Master as part of the Special Processing Unit (“SPU”), which is intended to expedite cases having a high likelihood of informal resolution. (ECF No. 10.) Petitioner filed medical records and other evidence marked as Exhibits 1-9 in November of 2021 and filed updated medical records marked as Exhibit 10 in September of 2022. (ECF Nos. 5, 15.)

Respondent filed his Rule 4 Report in May of 2023. (ECF No. 19.) In his report, respondent contended that petitioner had neither satisfied the Table criteria for SIRVA nor demonstrated a shoulder injury caused-in-fact by her vaccination. (*Id.* at 10-13.) Although respondent did not contend petitioner had any prior clinical history of shoulder pain or dysfunction, he argued that petitioner did not meet any of the three other SIRVA criteria, asserting that onset of shoulder pain did not arise within 48 hours of vaccination, that her pain was not limited to her shoulder, and that it was otherwise explained by glenohumeral osteoarthritis. (*Id.* at 10-11.) With respect to causation-in-fact, respondent stressed the lack of a medical opinion to support such a claim, but also contended that a cause-in-fact analysis should likewise lead to the conclusion that petitioner’s shoulder pain was due to osteoarthritis. (*Id.* at 13.)

Petitioner then filed an affidavit (Exhibit 11) and a motion for a ruling on the written record, seeking to be found entitled to compensation for a Table SIRVA. (ECF Nos. 20-21.) However, the Chief Special Master concluded that the motion was premature in that expert reports would likely be necessary. He found petitioner’s motion to be moot and reassigned the case to the undersigned for further litigation. (ECF No. 22.)

Thereafter, the parties filed expert reports, with Uma Srikumaran, M.D., opining on petitioner’s behalf (ECF No. 24; Exs. 12-13) and Geoffrey Abrams, M.D., opining on respondent’s behalf (ECF No. 27; Exs. A-B). I then issued a Rule 5 Order providing the parties preliminary guidance on a particular fact issue (discussed further in the Factual History, below) and also posed specific questions to each party’s expert. (ECF No. 28.) I advised the parties that, once their experts responded to my questions, the case would likely be ripe for resolution based on written submissions pursuant to Vaccine Rule 8(d). (*Id.*) The parties filed supplemental expert reports (ECF Nos. 30-31; Exs. 14, C), and then petitioner moved for a ruling on the written record, which has been fully briefed (ECF Nos. 33, 35-36).

In her motion, petitioner asserts that she has met her burden of proof with respect to the requirements for a Table Injury of SIRVA. (ECF No. 33, pp. 14-24.) Alternatively, she argues that she should be found entitled to compensation for a shoulder injury caused-in-fact by her vaccination based on an *Althen* analysis. (*Id.* at 24-30.) In response, respondent contends that petitioner has not preponderantly demonstrated that she meets either the second or fourth SIRVA criteria (*i.e.*, onset within 48 hours and that no other condition or abnormality explains her condition). (ECF No. 35, pp. 12-22.) Respondent further argues that petitioner has not presented a defined and recognized injury that would warrant an *Althen* analysis of causation-in-fact. (*Id.* at 27-28.) But, in any event, respondent contends that petitioner has not satisfied any of the three *Althen* prongs. (*Id.* at 28-34.) Of course, in her reply, petitioner seeks to rebut respondent's contentions on all of these points. (ECF No. 36.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve entitlement on the existing record. See Vaccine Rule 8(d); Vaccine Rule 3(b)(2); see also *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record").

III. Factual History

Petitioner received the flu vaccine at issue in her left deltoid on October 24, 2020. She was 66 years old at the time and respondent agrees she had no prior medical history of left shoulder pain, inflammation or dysfunction. (ECF No. 35, p. 2 (citing Ex. 1-2, 4; Ex. 5, pp. 33, 39-40, 126).) Petitioner, a hospice nurse, averred that she felt pain and burning in her left shoulder "within a few hours" of her vaccination, which worsened the next day, and she subsequently developed decreased shoulder mobility. (Ex. 11, p. 1.) However, she indicated that she attempted to manage her pain with Tylenol, NSAIDs, and rest for about three months, hoping the pain would resolve. (*Id.*)

Petitioner's initial post-vaccination medical encounter raised a factual issue. Petitioner initially presented to Certified Physician Assistant (P.A.-C) Rose on January 25, 2021, about three months post-vaccination. (Ex. 5, pp. 29-32.) The record documents a number of presenting complaints, but left shoulder pain was not among them. (*Id.* at 30.) However, petitioner filed an affidavit indicating not only that she did complain of left shoulder pain at this encounter, but also that P.A.-C Rose administered a steroid injection in her left shoulder. (Ex. 11, p. 1.) About a month later, on February 22, 2021, petitioner was seen by a sports medicine specialist, Dr. Kirk, for left shoulder pain. (Ex. 6, pp. 8-11.) Dr. Kirk specifically recorded that petitioner had previously been seen by P.A.-C Rose for her reported shoulder pain. (*Id.* at 8.) Petitioner was administered a steroid injection at her encounter with Dr. Kirk. (*Id.* at 10.)

In my Rule 5 Order, I advised the parties that the history recorded by Dr. Kirk was sufficient to confirm petitioner's recollection that she did report her shoulder pain to P.A.-C Rose on January 25, 2021, but that the record reflects that the complaint was

only incidentally discussed insofar as it was not listed among her chief complaints. (ECF No. 28, p. 2.) Additionally, the January 25, 2021 encounter record does not evidence the initial onset of her condition. (*Id.*) Petitioner's recollection that she was administered a steroid injection by P.A.-C Rose cannot reasonably be credited, especially in light of the injection being documented as occurring at her encounter with Dr. Kirk. (*Id.*) I offered the parties an opportunity to develop the record on this issue, but they advised in a joint status report that they would accept my finding on this issue as is. (ECF No. 29.)

At her February 22, 2021 encounter with Dr. Kirk, petitioner presented with a chief complaint of left shoulder pain, which she indicated "has been present for about 4 months and occurred after she got a flu shot." (Ex. 6, p. 8.) She described her pain as a 6 out of 10 and characterized it as "aching, burning, intermittent, [and] stabbing." (*Id.*) The pain, which was noted to be worse later in the day, radiated down the arm and worsened with activity, such as lifting. (*Id.*) She also described symptoms of stiffness, tenderness, and weakness. (*Id.*) On physical exam, inspection of the left shoulder was normal, but range of motion was mildly restricted in all planes. (*Id.* at 9.) She had moderate tenderness with palpation over the lateral aspect of the shoulder and mild tenderness over the anterior and posterior shoulder. (*Id.*) She also had mild pain and weakness on abduction and external rotation, as well as positive impingement tests (Neer's, Hawkin's, and empty can). (*Id.*) X-rays showed no acute abnormalities, but did show moderately severe glenohumeral joint space narrowing and small osteophytes at the humeral head. (*Id.*) Petitioner was diagnosed with both rotator cuff impingement syndrome and primary glenohumeral osteoarthritis. (*Id.* at 10.) However, Dr. Kirk felt petitioner's presentation, which was not focal to the glenohumeral joint, favored impingement as the explanation for her symptoms. (*Id.*) He intended to see how petitioner responded to treatment for impingement. (*Id.*) Petitioner was administered a therapeutic injection into her subacromial bursa, with a recommendation for a further injection into her glenohumeral joint if she did not experience relief. (*Id.*)

Petitioner then had several encounters with P.A.-C Rose in March of 2021 and an emergency department encounter in April of 2021 for epigastric abdominal pain. Shoulder pain was not documented at any of these encounters. (Ex. 5, pp. 22-29; Ex. 7, pp. 16-19.) Her March 8, 2021 encounter with P.A.-C Rose indicated, under Review of Systems, that petitioner had no complaints of muscle pain or weakness and, under Physical Exam, that she had normal strength and tone and normal range of motion in all extremities. (*Id.* at 28-29.) Her emergency department encounter also documented full range of motion. (Ex. 7, p. 16.) Shortly thereafter, petitioner established care with a new provider, P.A.-C Briggs. (Ex. 5, p. 15.) Petitioner had a number of complaints, including muscle cramps and generalized pain, but shoulder pain was not specifically discussed and she had a normal musculoskeletal exam. (*Id.* at 15-18.) A normal musculoskeletal exam was also noted during a May 4, 2021 follow up regarding her epigastric pain. (*Id.* at 13, 15, 62.)

Petitioner returned to Dr. Kirk on May 5, 2021. (Ex. 6, p. 55.) Dr. Kirk recorded substantially the same history he had recorded on February 22, 2021, and additionally

noted that petitioner did not find the steroid injection to have been helpful “at all.” (*Id.*) Physical exam was substantially the same. (*Compare id.* at 55-56, *with id.* at 9.) Although Dr. Kirk did not remove impingement from his assessment, he now considered it a lesser diagnosis and favored osteoarthritis as the primary source of her symptoms, given that the subacromial injection had not provided any relief. (*Id.* at 56.) Dr. Kirk ordered a left shoulder MRI and advised petitioner to continue strengthening and range of motion exercises. (*Id.*) Petitioner deferred a recommended glenohumeral joint injection. (*Id.*) Petitioner underwent an MRI of the left shoulder on May 13, 2021. (*Id.* at 53-54.) The impression from the radiologist was: (1) Severe glenohumeral osteoarthritis with a small joint effusion with synovitis; (2) Supraspinatus moderate tendinosis involving the interstitial and critical zone fibers with tearing; (3) Subscapularis and infraspinatus tendinosis; and (4) Moderate acromioclavicular osteoarthritis. (*Id.* at 54.)

Based on his review of the MRI results, Dr. Kirk recommended a reverse shoulder replacement due to the severe arthritis and rotator cuff pathology and referred her to Dr. Parry. (Ex. 6, p. 51.) However, petitioner’s insurance denied coverage unless petitioner first underwent physical therapy (*Id.* at 34), which she began on June 4, 2021 (*Id.* at 34, 37). (She also had unrelated medical encounters in the interim.) At her physical therapy evaluation, petitioner attributed her shoulder pain to her vaccination, though onset is not specifically detailed. (*Id.* at 37.) Petitioner reported that she was still mostly able to complete her duties as a hospice nurse, as well as her activities of daily living; however, she did have difficulty reaching up or reaching forward. (*Id.*) Petitioner was worried about developing a frozen shoulder. (*Id.*) When petitioner first consulted with Dr. Parry on June 7, 2021, he recorded that her condition “came on suddenly without known injury,” but noted that “[s]he started noticing her pain after she received her flu shot in that arm.” (*Id.* at 34.) Petitioner complained that the physical therapy was too painful to continue. (*Id.* at 34, 36.) It was noted that petitioner would continue with the plan for surgery. (*Id.* at 36.)

Petitioner underwent a reverse total shoulder arthroplasty on June 16, 2021. (Ex. 5, p. 160.) The preoperative diagnosis was rotator cuff arthropathy, which did not change postoperatively. (*Id.*) Although Dr. Kirk had initially recommended surgery in part due to petitioner’s severe arthritis, Dr. Parry’s operative report did not include arthritis as among the indications for the procedure. (*Id.*) (However, as discussed below, both parties’ experts explain that the shoulder replacement was indicated due to petitioner’s osteoarthritis. (Ex. 14, pp. 2-3; Ex. C, p. 3.)) At her two-week postoperative follow up, petitioner was still using a sling, but reported progressively less pain since the surgery. (Ex. 6, p. 94.) At her six week follow up, petitioner reported that she was no longer taking any pain medication and was advised that she could discontinue use of the sling. (*Id.* at 99, 101.) Petitioner was advised to be cautious, but was told she could continue to expect improvement over 12-18 months. (*Id.* at 101-02.) Petitioner attended postoperative physical therapy from July 27, 2021, until September 2, 2021. (Ex. 8.) At the conclusion of physical therapy, petitioner had active range of motion that was within normal limits, but her flexion remained limited and she continued to complain of soreness and weakness, especially with overhead exercises. (*Id.* at 45.)

At her final post-operative follow up on September 7, 2021, about three months after her surgery, petitioner was reportedly “totally amazed” at her results. (Ex. 6, p. 107.) She was doing well and was instructed to follow up again at the one-year mark. (*Id.*) In her later affidavit, petitioner averred that she still had limited range of motion at this encounter, though she “was generally satisfied with [her] progress” at that time. (Ex. 11, p. 3.)

About one year following her surgery, petitioner returned to care complaining of a “few months” of pain that radiated into her neck and down her arm, though she denied numbness or tingling. (Ex. 10, p. 6.) Petitioner did not recall injuring her shoulder. (*Id.*) After x-ray and physical exam, there was no concern that her shoulder replacement had been loosening. (*Id.* at 8.) She was started on an anti-inflammatory medication, and physical therapy was recommended. (*Id.*) However, petitioner confirmed in her affidavit that she did not pursue this physical therapy, opting instead for home exercises (Ex. 11, p. 3), and no further medical records have been filed. As of May 17, 2023, petitioner avers that she still has pain and dysfunction of her left shoulder that does cause difficulty with her activities of daily living. (*Id.*) She feels her left shoulder “will never be the same again.” (*Id.*)

IV. Expert Opinions

a. Uma Srikumaran, M.D., for petitioner³

Based on his review of petitioner’s history, Dr. Srikumaran believes petitioner had no relevant history of shoulder pain or dysfunction and that her shoulder pain began within 48 hours of her vaccination. (Ex. 12, pp. 5-6.) He acknowledges that petitioner’s initial presentation included a report of pain that “radiate[d] down the arm,” but contends that, due to the complexity of the shoulder’s interconnectivity to adjacent parts of the body, injury to the shoulder joint can result in pain complaints relative to the surrounding musculature, including the arm. (*Id.* at 7 (alteration in original).) Thus, he opines that

³ Dr. Srikumaran received his medical degree from Johns Hopkins University School of Medicine (“Johns Hopkins”) in 2005, before going on to complete an internship in general surgery and orthopedic surgery and a residency in orthopedic surgery at Johns Hopkins Hospital in 2006 and 2010, respectively. (Ex. 13, p. 1.) From there, Dr. Srikumaran completed a fellowship in shoulder surgery at Harvard, Massachusetts General Hospital in 2011, before returning to Johns Hopkins as an assistant professor of orthopedic surgery that same year. (*Id.* at 1-2.) He was elevated to associate professor of orthopedic surgery in 2019. (*Id.* at 2.) Dr. Srikumaran worked briefly as an assistant team physician for the Baltimore Orioles, the Medical Director at Howard County Johns Hopkins Orthopedic Surgery, the chair of the Department of Orthopedic Surgery and the Medical Director of the Joint Academy at Howard County General Hospital, and the Medical Director of the Musculoskeletal Service Line-Columbia. (*Id.*) He currently maintains positions as the Director of the Shoulder Fellowship in the Department of Orthopedic Surgery at Johns Hopkins, Medical Director of Johns Hopkins Ambulatory Surgery Center, and Vice Chair-Quality, Safety, and Service in the Department of Orthopedic Surgery at Johns Hopkins. (*Id.*) Dr. Srikumaran is a board-certified orthopedic surgeon, and he maintains an active medical license in Maryland. (*Id.* at 16.) Throughout his career, Dr. Srikumaran has, among other things, authored over 100 pieces of original research, 8 review articles, 5 case reports, and over 50 book and book chapters. (*Id.* at 2-13.)

an isolated report of pain extending down into the arm is not incompatible with SIRVA, stressing that at the same encounter at which petitioner reported this radiating pain, she was diagnosed as having rotator cuff impingement syndrome. (*Id.* (citing Ex. 6, pp. 8, 10).) Accordingly, he opines that petitioner's history is consistent with the first three table requirements for a SIRVA. (*Id.* at 5.) Dr. Srikumaran stresses that patients should be trusted when they are able to identify a trigger for shoulder pain. (*Id.* at 6.)

Regarding the fourth criterion, Dr. Srikumaran acknowledges that it is "important to address the petitioner's underlying glenohumeral arthritis." (Ex. 12, p. 7.) As a degenerative condition, it takes decades to develop. (*Id.*) Yet, petitioner was asymptomatic prior to vaccination. (*Id.*) According to Dr. Srikumaran, in many patients, shoulder arthritis can remain silent until a trigger causes activation of pain. (*Id.*) In this case, he opines that petitioner initially suffered vaccine-related inflammation of the bursal and synovial tissue, noting that Dr. Kirk initially favored impingement syndrome, rather than glenohumeral arthritis, as the source of her pain. (*Id.* at 7-8 (citing Ex. 6, p. 60).) Petitioner's inflamed bursal and synovial tissue then in turn triggered her previously asymptomatic glenohumeral arthritis to become painful, even though it did not cause it. (*Id.* at 8.) Thus, Dr. Srikumaran opines that petitioner's condition satisfies all four of the criteria for a Table SIRVA. (*Id.*)

Dr. Srikumaran opines that this understanding is consistent with the evolution of Dr. Kirk's assessment from initially attributing petitioner's pain primarily to impingement syndrome to later attributing it primarily to osteoarthritis. (Ex. 14, p. 2.) Even if petitioner's subacromial injection had offered some relief, the fact that her osteoarthritis was becoming aggravated would explain why her pain continued, with the arthritic pain overcoming the pain from the bursitis. (*Id.*) Additionally, the fact that petitioner's subsequent MRI showed no evidence of bursitis would also be consistent with the notion that the subacromial injection had been effective. (*Id.*) He surmises that, if it had been done earlier, it would have shown bursitis. (*Id.* at 4.) Dr. Srikumaran indicates that "I believe her initial conglomerate of symptoms was consistent with subacromial bursitis and impingement syndrome." (*Id.*) However, he notes that "impingement syndrome is a generalized term and can be secondary to many physiologic causes that affect the subacromial space such as subacromial bursitis (which the petitioner had physical exam findings of), rotator cuff tendinitis, calcific tendinitis and even glenohumeral arthritis." (*Id.*)

Dr. Srikumaran explains that shoulder joint replacement such as petitioner underwent is an "excellent surgery" for patients with moderate to severe osteoarthritis. (Ex. 14, pp. 2-3.) He opines that it was "appropriately indicated" in petitioner's case. (*Id.* at 3.) "When her symptoms and physical exam findings are taken together with the level of arthritis identified on MRI, the best surgical option is a shoulder replacement," even though a more limited bursectomy would have been the appropriate treatment to remove the vaccine irritant. (*Id.*) However, in his opinion, although the surgery was indicated because of petitioner's chronic arthritis, the initiating event was still the

vaccination. In effect, he opines that petitioner's surgery, while in treatment of her osteoarthritis, is not informative of the initial cause of her condition.⁴

Dr. Srikumaran also suggests that petitioner's shoulder condition can be shown to have been caused-in-fact by her vaccination. (Ex. 12, pp. 8-9.) He presents a theory of causation whereby the injection of vaccine antigen into the subacromial bursa leads to an inflammatory response that can activate pathologic changes in the subacromial space, biceps tendon, glenohumeral joint, and/or capsulitis. (*Id.* (citing Marko Bodor & Enoch Montalvo, *Vaccination-Related Shoulder Dysfunction*, 25 VACCINE 585 (2007) (Ex. 12, Tab D); S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049 (2010) (Ex. 12, Tab A), L.H. Martín Arias et al., *Risk of Bursitis and Other Injuries and Dysfunctions of the Shoulder Following Vaccinations*, 35 VACCINE 4870 (2017) (Ex. 12, Tab B); C. Trollmo et al., *Intra-Articular Immunization Induces Strong Systemic Immune Response in Humans*, 82 CLINICAL & EXPERIMENTAL IMMUNOLOGY 384 (1990) (Ex. 12, Tab S); D. C. Dumonde & L. E. Glynn, *The Production of Arthritis in Rabbits by an Immunological Reaction to Fibrin*, 43 BRIT. J. EXPERIMENTAL PATHOLOGY 373 (1962) (Ex. 12, Tab G); Julia R. Hirsiger et al., *Chronic Inflammation and Experimental Matrix-Specific Autoimmunity Following Inadvertent Periarticular Influenza Vaccination*, 124 J. AUTOIMMUNITY 102714 (2021) (Ex. 12, Tab N)).⁵ Following on from this theory, Dr. Srikumaran's explanation of a logical sequence of cause and effect mimics his discussion of petitioner's condition relative to the fourth SIRVA criterion. (*Id.* at 9.) Asked whether there is any evidence to suggest that vaccination can aggravate osteoarthritis, Dr. Srikumaran indicated that the Dumonde study, which is a rabbit model study, is the only available evidence to suggest that an immunologic reaction to antigenic material can result in arthritis. (Ex. 14, p. 4 (discussing Dumonde & Glynn, *supra*, at Ex. 12, Tab G).) However, when taken with the other literature of record showing various changes in joint tissue following vaccination, Dr. Srikumaran opines that the evidence shows that the inflammatory response to vaccination is capable of infiltrating all areas of the shoulder and that underlying arthritis can be affected by vaccination injuries. (*Id.* at 5.)

⁴ Dr. Srikumaran offers the analogy of a car tire. A worn tire tread may not come to attention on its own if it is not causing any problems. However, if a driver runs over a nail, the tire may deflate quickly, bringing the tire to a mechanic's attention. Due to the presence of the worn tread, the mechanic may recognize the need to replace the tire altogether, rather than perform a more limited repair to patch the puncture; however, the nail was still nonetheless the cause of the deflated tire. According to Dr. Srikumaran, petitioner's chronic arthritis is equivalent to the worn tire tread, while her vaccination plays the same role as the nail. A bursectomy would be equivalent to repairing the puncture, whereas petitioner's joint replacement is equivalent to a tire replacement that simply obviated the need to repair the puncture. (Ex. 14, p. 3.)

⁵ These are the publications Dr. Srikumaran cited in a case-specific discussion of his theory of causation. At the end of his first report, he also included a broader, generic discussion of a theory by which vaccination can lead to SIRVA. That discussion cited additional literature. (Ex. 12, pp 10-15.) Although I have reviewed that literature, it is not necessary to separately address it.

b. Geoffrey Abrams, M.D., for respondent⁶

Based on his review of petitioner's history, Dr. Abrams opines that petitioner's shoulder pain is likely explained by her imaging-confirmed arthritis and that a SIRVA is an unlikely diagnosis. (Ex. A, p. 4.) Dr. Abrams stresses that arthritis is a very common cause of shoulder pain, especially in those over 50 years of age. (*Id.* (citing Claudio Chillemi & Vincenzo Franceschini, *Shoulder Osteoarthritis*, ARTHRITIS, Jan. 2013, at 1 (Ex. A, Tab 1)).) It is a slow process that takes years to develop. (*Id.*) He disagrees that patients can reliably identify a trigger for arthritic symptoms. While this may be true for traumatic events, such as falls or accidents, it is not necessarily true of shoulder pain more broadly. Most patients are unable to recall a specific triggering event. (*Id.*) Dr. Abrams stresses that "everyday activities (i.e. carrying groceries, sleeping on the shoulder, and other normal activities which patients do not recognize as traumatic) can initiate pain from shoulder arthritis." (*Id.*) In petitioner's case, he urges that the reliability of her recollection that her shoulder pain began following vaccination should be questioned in light of her delay in seeking treatment. (*Id.* at 6-7.) He notes that petitioner's initial x-rays showed osteophytes, which could not have developed within the four months between the time of petitioner's vaccination and her x-rays. (*Id.* at 4.)

Dr. Abrams opines that the following points support arthritis as the cause of petitioner's shoulder pain:

- Findings on physical exam of range of motion "mildly restricted through all planes"; and
- No significant positive response to a subacromial steroid injection; and
- X-ray and MRI findings of "severe osteoarthritis"; and
- A lack of any finding of subacromial/subdeltoid bursitis upon MRI; and
- Her reverse shoulder replacement surgery, which confirms Dr. Kirk believed arthritis to be the source of her pain.

(Ex. A, pp. 4-5 (citing Ex. 6, pp. 9, 54; Ex. 5, p. 55); Ex. C, p. 3.)

Dr. Abrams endorses Dr. Kirk's conclusion as the treating orthopedist that the failure of petitioner's subacromial injection to alleviate her symptoms pointed away from subacromial inflammation and toward osteoarthritis as the source of petitioner's pain.

⁶ Dr. Abrams received his medical degree from the University of California, San Diego, in 2007, before going on to complete a surgical internship in the Department of General Surgery at Stanford University Hospital and Clinics in 2008, as well as a residency in the Department of Orthopedic Surgery also at Stanford University Hospital and Clinics in 2012. (Ex. B, p. 1.) Dr. Abrams went on to complete a fellowship in orthopedic sports medicine at Rush University Medical Center, where he also worked as a clinical instructor, in 2013. (*Id.*) From there, Dr. Abrams worked as an assistant physician at the Veterans Administration Hospital, Palo Alto; an assistant professor at Stanford University School of Medicine; and Director of Lacob Sports Medicine Clinic at Stanford University School of Medicine. (*Id.*) He is a board-certified orthopedic surgeon, and he maintains an active medical license in California. (*Id.* at 2.) Throughout his career, Dr. Abrams has authored over 150 peer-reviewed publications and abstracts, nearly 30 podium and poster presentations, 5 commentaries, and 26 book chapters. (*Id.* at 2-22.)

(Ex. A, p. 5 (citing Ex. 6, pp. 9, 56).) He disagrees with Dr. Srikumaran's suggestion that the source of petitioner's pain changed between her initial February orthopedic evaluation and her later evaluation, stressing that the physical exam findings, which he opines support osteoarthritis, remained essentially the same at both encounters. (*Id.*) He also explains that signs of impingement cannot be equated to a diagnosis of bursitis, as Dr. Srikumaran does. (Ex. C, pp. 3-4.) Dr. Abrams indicates that "[s]houlder exams can be variable from patient to patient and also from examiner to examiner. The fact that [petitioner] had pre-existing arthritis makes her susceptible to many positive exam findings, including those associated with impingement and bursitis." (*Id.*) Other objective evidence is necessary to distinguish the cause of positive impingement signs and, here, that objective evidence, including petitioner's MRI and lack of response to a subacromial injection, points away from bursitis. (*Id.* at 4.)

Dr. Abrams acknowledges that "arthritis itself is an inflammatory condition, so once the process is initiated it can often lead to chronic symptoms and pain." (Ex. A, p. 4 (footnote omitted) (citing Michelle Xiao et al., *Inflammatory Mechanisms in the Development of Osteoarthritis* (unpublished manuscript) (Ex. A, Tab 2)).) However, he characterizes the suggestion of post-vaccination bursitis initiating arthritic pain as "not a known clinical entity" and disagrees that the inflammatory response in SIRVA can move from the subacromial space to other areas of the shoulder, such as the rotator cuff and glenohumeral joint. (*Id.* at 5.) He explains that the supraspinatus tendon presents a barrier between the subacromial and intra-articular spaces and, in petitioner's case, her MRI showed that she had no significant tearing of the rotator cuff, meaning it is unlikely antigenic material could have reached the intra-articular space where her arthritis was located. (Ex. C, pp. 2-3.) Without any antigenic material within the intra-articular space, there would be no biological mechanism for the vaccine to cause inflammation in that area. (*Id.* at 5.) Dr. Abrams stresses that both the Dumonde and Trollmo studies cited by Dr. Srikumaran involved intra-articular injections. (*Id.* at 4 (citing Dumonde & Glynn, *supra*, at Ex. 12, Tab G; C. Trollmo et al., *supra*, at Ex. 12, Tab S).) Accordingly, they do not constitute evidence that an intra-muscular injection could lead to joint arthrosis. (*Id.*)

V. Analysis

a. Table Injury of SIRVA

As discussed above, petitioner is entitled to a presumption of causation if she can establish that her injury arose within 48-hours of vaccination and meets the specific criteria that define what constitutes a Table "SIRVA." 42 CFR § 100.3(c)(10). Under the Vaccine Act, a petitioner bears the burden of demonstrating the factual underpinnings of her claim by a preponderance of the evidence. § 300aa-13(1)(a). Thus, she must demonstrate each of the four SIRVA QAI criteria by preponderant evidence. In this case, I find that petitioner cannot meet the fourth SIRVA QAI criterion, and this is therefore dispositive of her Table claim.

The fourth SIRVA criterion requires that “[n]o other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, and any other neuropathy).” 42 CFR § 100.3(c)(10)(iv). This element of petitioner’s showing “requires consideration of a petitioner’s medical condition as a whole.” *Record v. Sec’y of Health & Human Servs.*, No. 21-1312V, 2025 WL 868957, at *6 (Fed. Cl. Feb. 26, 2025). However, while the “other condition or abnormality” at issue must qualify as an explanation for the petitioner’s symptoms, it “need not be a better or more likely explanation.” *French v. Sec’y of Health & Human Servs.*, No. 20-0862V, 2023 WL 7128178, at *6 (Fed. Cl. Spec. Mstr. Sept. 27, 2023). Indeed, a petitioner may fail to meet the fourth SIRVA criterion even where there is clinical evidence of an alternative condition that falls short of a definitive diagnosis. *Durham v. Sec’y of Health & Human Servs.*, No. 17-1899V, 2023 WL 3196229, at *14 (Fed. Cl. Spec. Mstr. May 2, 2023) (noting that the regulation cites “clinical evidence of” various conditions).

However, respondent does not defeat a Table SIRVA claim “simply by noting the presence of shoulder dysfunction beyond deltoid bursitis.” *Grossman v. Sec’y of Health & Human Servs.*, No. 18-00013V, 2022 WL 779666, at *16 (Fed. Cl. Spec. Mstr. Feb. 15, 2022). Because SIRVA is itself broadly defined as an unspecified musculoskeletal injury affecting the shoulder (42 C.F.R. § 100.3(c)(10)), alternative explanations based on conditions or abnormalities intrinsic to the shoulder raise a potentially more difficult question. See *Lang v. Sec’y of Health & Human Servs.*, No. 17-995V, 2020 WL 7873272, at *12-13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020); see also *Durham*, 2023 WL 3196229, at *14 n.11. A finding that a petitioner has arthritis affecting the shoulder does not *per se* preclude a finding that a Table SIRVA exists. *Lang*, 2020 WL 7873272, at *13. Rather, in that context the question is “whether petitioner’s own clinical history indicates that her shoulder pathology wholly explains her symptoms independent of vaccination.” *Id.*; see also, e.g., *Molina v. Sec’y of Health & Human Servs.*, No. 20-845V, 2024 WL 4223393, at *8 (Fed. Cl. Spec. Mstr. Aug. 15, 2024) (finding that petitioner’s diagnosis of calcific tendinitis precluded a Table SIRVA under the fourth SIRVA criterion because it is “a condition that can in itself present with acute onset of shoulder pain”). Ultimately, where the presence of another condition is apparent, petitioner bears the burden of proving that the condition nonetheless “would not explain” her symptoms. *Durham*, 2023 WL 3196229, at *14.

Here, petitioner’s treating orthopedist, Dr. Kirk, initially found that petitioner had evidence of both impingement syndrome affecting her subacromial space and glenohumeral osteoarthritis. (Ex. 6, p. 10.) He first felt that her symptoms were more likely the result of her impingement syndrome (*Id.*); however, after her condition failed to respond to a subacromial steroid injection, he concluded that her glenohumeral osteoarthritis was the more likely cause of her shoulder pain (*Id.* at 56). On respondent’s behalf, Dr. Abrams agrees with this conclusion. (Ex. A, p. 5.) Additionally, while Dr. Srikumaran proposes an initiating role for bursitis, he ultimately opines that any bursitis that was present would have resolved between petitioner’s February and May 2021 orthopedic encounters, and that her pain from that point forward was due to osteoarthritis. (Ex. 12, pp. 7-8.) Both parties’ experts agree that petitioner’s ultimate

treatment for her condition – her reverse shoulder replacement – was indicated due to the presence of osteoarthritis that failed conservative treatment measures. (Ex. 14, pp. 2-3; Ex. C, p. 3.) Given all this, petitioner cannot reasonably assert that her glenohumeral osteoarthritis “would not” explain her symptoms.

Dr. Srikumaran nonetheless opines that petitioner’s osteoarthritis would not wholly explain her clinical history absent the additional involvement of her vaccination. However, this is not persuasive on this record. Dr. Srikumaran’s opinion is based on the speculative assumption that petitioner suffered transitory (vaccine-caused) bursitis that fully responded to treatment and therefore evaded any detection apart from petitioner’s initial signs of impingement upon physical examination. Importantly, however, both experts explain that impingement signs are not specific to bursitis and can be caused by a number of conditions, including glenohumeral osteoarthritis, which Dr. Kirk identified as additionally present from the time of petitioner’s first encounter. (Ex. 14, p. 4; Ex. C, pp. 3-4.) Moreover, Dr. Abrams stresses that petitioner’s physical exam findings were substantially the same at both her February and May 2021 orthopedic encounters – that is, both before and after the subacromial injection Dr. Srikumaran posits as an explanation for the disappearance of petitioner’s bursitis. (Ex. A, p. 5.) Even accepting that what Dr. Srikumaran proposes is *possible*, Dr. Abrams is persuasive in stressing that impingement signs cannot be merely equated with bursitis and that an actual diagnosis of bursitis should have some objective confirmation, which is entirely lacking in this case. (Ex. C, pp. 3-4; Ex. A, p. 5.) Therefore, given the lack of any other supporting evidence and the presence of confirmed glenohumeral osteoarthritis, bursitis is not a likely explanation for petitioner’s signs of impingement.

Finally, the fact that petitioner’s pain first arose in the post-vaccination period is not dispositive. Although both experts agree that the degenerative changes underlying osteoarthritis develop over years (Ex. 12, p. 7; Ex. A, p. 4), onset of pain does not necessarily likewise occur gradually. Dr. Abrams explained that “everyday activities (i.e. carrying groceries, sleeping on the shoulder, and other normal activities which patients do not recognize as traumatic) can initiate pain from shoulder arthritis” even as the majority of patients cannot identify the trigger of their pain. (Ex. A, p. 4.) Although Dr. Srikumaran sought to defend the reliability with which petitioner identified her own vaccination as a trigger for her pain, he did not dispute this broader understanding of osteoarthritis onset as discussed by Dr. Abrams. (Ex. 14, pp. 1-2.) To be clear, this consideration is not to be confused with petitioner’s separate burden of demonstrating under the second SIRVA criterion that her pain arose within 48 hours of vaccination. Even assuming *arguendo* that petitioner met her burden of proof under the second criterion, the issue here would still be that she has not preponderantly demonstrated that the pattern of onset she experienced is incompatible with glenohumeral osteoarthritis being the explanation for her symptoms irrespective of her vaccination.

For all these reasons, petitioner has not preponderantly demonstrated the presence of a Table SIRVA.

b. Shoulder Injury Caused-in-Fact by Vaccination

Even having failed to meet the specific requirements for a Table Injury of SIRVA, petitioner could still demonstrate, pursuant to the *Althen* test, that her shoulder injury was nonetheless caused-in-fact by her vaccination. However, I do not find that petitioner has met her preponderant burden of proof under either *Althen* prongs one (a medical theory of causation) or two (a logical sequence of cause and effect).

Under *Althen* prong one, petitioner must provide a “reputable medical theory,” demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (quoting *Pafford v. Sec’y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff’d*, 64 Fed. Cl. 19 (2005), *aff’d*, 451 F.3d 1352 (Fed. Cir. 2006)). Such a theory must only be “legally probable, not medically or scientifically certain.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549-49 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, “[a] petitioner must provide a ‘reputable medical or scientific explanation’ for [her] theory. While it does not require medical or scientific certainty, it must still be ‘sound and reliable.’” *Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (citation omitted) (quoting *Knudsen*, 35 F.3d at 548-49).

Dr. Srikumaran theorizes that an inflammatory reaction in the subacromial space, consistent with what is generally believed to occur in the context of SIRVA, can ultimately spread to affect the glenohumeral space to aggravate osteoarthritis from an asymptomatic state to a painful state. (Ex. 12, pp. 8-9.) This theory initially appears intuitive insofar as Dr. Abrams agrees that arthritis is inflammatory and can be activated to become chronically painful by otherwise ordinary daily events. (Ex. A, p. 4.) Moreover, it has been observed that needle penetration into the glenohumeral space is possible given its proximity to the deltoid muscle. (Martín Arias et al., *supra*, at Ex. 12, Tab B, p. 5). However, while the SIRVA literature filed in this case indicates that a small percentage (5.2%) of SIRVA sufferers do have MRI findings of glenohumeral arthritis (Elisabeth M. Hesse et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner Claims to the National Vaccine Injury Compensation Program, 2010-2016*, 38 VACCINE 1076 (2020) (Ex. 12, Tab K, p. 5 tbl.5)), it does not suffice without more to demonstrate that glenohumeral arthritis is a pain generator among these individuals, rather than an incidental finding. Based on the case series by Bodor and Montalvo, it has been observed that SIRVA can affect the glenohumeral space. (Atanasoff et al., *supra*, at Ex. 12, Tab A, p. 2 (citing Bodor & Montalvo, *supra*, at Ex. 12, Tab D).) However, both of the Bodor and Montalvo subjects had issues with “multiple shoulder structures,” including the glenohumeral joint, but also beyond the glenohumeral joint, and neither subject was diagnosed with active osteoarthritis in particular. (Bodor & Montalvo, *supra*, at Ex. 12, Tab D, pp. 2-3.) Instead, the literature suggests that when a vaccine is inadvertently injected into the glenohumeral space, it results in “an intense

immune and inflammatory response” that leads to damage and dysfunction such as edema, erosion, and necrosis (Martín Arias et al., *supra*, at Ex. 12, Tab B, pp. 5-6), which is a different presentation than simple activation of preexisting osteoarthritis.

After Dr. Srikumaran initially raised this theory based primarily on an animal model study (namely, the study by Dumonde and Glynn), my Rule 5 order prompted him, in light of Dr. Abrams’s competing opinion that it did not represent any known clinical entity, to identify what evidence is available to indicate that vaccinations can activate glenohumeral osteoarthritis in humans. (ECF No. 28, p. 3.) In response, he indicated that the Dumonde study “is the only study of its kind to demonstrate production of arthritis as the result of antigenic material.” (Ex. 14, p. 4.) Thus, although the Dumonde study is not the only evidence Dr. Srikumaran cites, it is the linchpin of his theory. *Accord Clark v. Sec’y of Health & Human Servs.*, No 18-813V, 2022 WL 16635681, at *26 (Fed. Cl. Spec. Mstr. Feb. 7, 2022) (noting in a prior SIRVA case that “[n]one of the literature filed in this case supports the idea that those investigating acute post-vaccination shoulder injuries suspected an autoimmune etiology to explain their findings of acute shoulder pain whereas the literature Dr. Axelrod cites purporting to show potential molecular mimics within joint tissue involves the separate context of chronic conditions such as rheumatoid arthritis and osteoarthritis” (footnote omitted)).

However, the purpose of the Dumonde study, which was conducted in 1961, was to develop an animal model of experimental immune-mediated arthritis resembling rheumatoid arthritis at a time when it remained uncertain whether rheumatoid arthritis was an immune disease. (Dumonde & Glynn, *supra*, at Ex. 12, Tab G, pp. 1, 14.) The authors concluded that they had experimentally provoked an arthritis in the subject rabbits that “bears a striking resemblance to rheumatoid arthritis.” (*Id.* at 16.) Especially given that time has borne out the hypothesis that rheumatoid arthritis is an autoimmune condition, Dr. Srikumaran has not substantiated that the Dumonde findings are informative with respect to osteoarthritis. Moreover, even where rheumatoid arthritis has been accepted as an autoimmune condition, petitioners have not necessarily been persuasive in seeking to demonstrate that it can be caused by the flu vaccine. *E.g.*, *Casazza v. Sec’y of Health & Human Servs.*, No. 17-947V, 2023 WL 6214984, at *13 (Fed. Cl. Spec. Mstr. Aug. 30, 2023) (explaining that petitioner’s expert was unpersuasive as to *Althen* prong one where he “presented a description of the autoimmune process involved in [rheumatoid arthritis] that does not itself implicate vaccines, a separate concept by which any vaccine might in general contribute to autoimmunity without respect to any specific context, and precious little that could tie the two together”).

Additionally, Dr. Abrams observes that a significant limitation of the Dumonde study vis-à-vis Dr. Srikumaran’s theory is that the study’s findings resulted from intra-articular injections. (Ex. C, p. 4 (discussing Dumonde & Glynn, *supra*, at Ex. 12, Tab G, p. 12).) Thus, in that study, the findings resulted from direct exposure to inflammatory antigenic material. (*Id.*) However, that is not what Dr. Srikumaran hypothesizes in this case. Moreover, as noted above, the SIRVA literature otherwise correlates needle penetration of the glenohumeral joint with more severe damage than simply activation of

pre-existing osteoarthritis. (Martín Arias et al., *supra*, at Ex. 12, Tab B, p. 5.) The Dumonde findings do not readily support Dr. Srikumaran's theory that inflammation stimulated by antigenic material within the subacromial bursa would spread to the separate glenohumeral space, especially given that the two spaces are separated by the supraspinatus tendon as Dr. Abrams otherwise observes. (Ex. C, pp. 2-5.) Thus, even if one accepted the Dumonde study as some evidence supporting the notion that an antigenic challenge could activate osteoarthritis, it would still fail to provide evidence supporting any interplay between post-vaccination bursitis and glenohumeral osteoarthritis.

Accordingly, I cannot conclude that petitioner has presented a reliable theory of causation under *Althen* prong one to implicate her flu vaccination as a cause of her symptoms of glenohumeral osteoarthritis.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to significant weight. *Andreu*, 569 F.3d at 1375; *Capizzano*, 440 F.3d at 1326 (stating that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'" (alteration in original) (quoting *Althen*, 418 F.3d at 1280)). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. See § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009) (stating that "there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). Ultimately, petitioner may support her claim either through her medical records or by expert opinion. § 300aa-13(a)(1).

Here, Dr. Srikumaran's explanation of a logical sequence of cause and effect purporting to implicate petitioner's vaccination as a cause of her condition is essentially the same as his explanation as to why her diagnosed osteoarthritis should not prevent her from demonstrating the table requirements for SIRVA. (*Compare* Ex. 12, pp. 7-8, *with id.* at 9.) Accordingly, the same reasoning that prevents petitioner from meeting the Table requirements (see section V.a., *supra*), equally hinders her demonstration of causation-in-fact. In particular, as explained above, Dr. Srikumaran's predicate assumption that petitioner initially suffered bursitis, as called for by his theory of causation, is unsupported speculation. Moreover, under *Althen* prong two, treating physician opinions carry significant weight. Here, however, although petitioner reported her post-vaccination onset of shoulder pain to Dr. Kirk, he never opined that her condition was vaccine caused. Additionally, once petitioner's condition failed to resolve

following a subacromial injection, he explicitly opined that petitioner's osteoarthritis was the more likely cause of her pain. (Ex. 6, p. 56.) And, finally, even if Dr. Srikumaran's theory were correct, Dr. Abrams further questions whether any sequence of cause and effect would be possible in petitioner's own case, given that she had no full thickness rotator cuff tear that could potentially expose the glenohumeral space to the inflammatory response purportedly beginning within the subacromial space. (Ex. C, pp. 2-5.)

For all these reasons, petitioner has not presented preponderant evidence of a logical sequence of cause and effect demonstrating that her vaccine was a cause of her shoulder pain. Even assuming *arguendo* that petitioner met her burden of proof under *Althen* prong three by demonstrating that onset of her shoulder pain occurred shortly after her vaccination, her failure to meet her burden of proof under *Althen* prongs one and two is dispositive. *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury"), *aff'd per curiam sub nom. Veryzer v. United States*, 475 F. App'x 765 (Fed. Cir. 2012); *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to prong two when respondent conceded that petitioner met prong three).

VI. Conclusion

Petitioner has my sympathy for what she has endured. However, considering the record as a whole under the standards applicable in this program, petitioner has not preponderantly established either that her October 24, 2020 flu vaccination resulted in a Table SIRVA or alternatively caused-in-fact a shoulder injury. Accordingly, petitioner is not entitled to compensation. Therefore, this case is dismissed.⁷

IT IS SO ORDERED.

s/Daniel T. Horner

Daniel T. Horner

Special Master

⁷ In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.